

matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

Claims 33, 44, and 53-88 remain rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Office asserts that probes and/or primers which are "specific" to the elected sequences, beyond the exact complementarity and lengths of the elected sequences are included but not disclosed as to written description.

Applicants respectively traverse this ground for rejection. As noted above, claims 33, 44, and 53-88 have been cancelled and claims 89-106 have been newly added. Within the context of the claimed methods for detecting breast cancer, one of skill in the art would readily understand primers and probes that are "specific" for the claimed polynucleotide sequences. Such probes and primers encompass oligonucleotides that hybridize to the specifically recited sequences without significant hybridization to other polynucleotides, *e.g.*, without hybridization to other polynucleotides at levels that would substantially compromise efficacy of the oligonucleotide for its intended use. Applicants submit that one of skill in the art would appreciate that the precise sequence of the oligonucleotides could be varied depending upon the conditions employed for hybridization while still being sufficiently specific for the recited sequences so as to be useful in the diagnostic embodiments of the invention. However, newly added claims 89-106 recite oligonucleotide primers and probes that are specific for the claimed SEQ ID NOs: and further comprise at least about 10 contiguous nucleotides of the claimed SEQ ID NOs:. Applicants respectfully submit that the above amendments and comments obviate and overcome the rejection and request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

Claims 33, 44, 53-88 remain rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claims the subject matter which Applicants regard as the invention. The Office asserts that the claims are vague and indefinite in the phrases "about 10 to 40" and "complements".

Applicants respectively traverse this ground for rejection. Applicants do not acquiesce to the Office's rejection of the use of these terms. However as discussed above, claims 33, 44, 53-88 have been cancelled. Newly added claims 89-97 recite oligonucleotide primers that are specific for the claimed SEQ ID NOs: or the corresponding complements of the claimed SEQ ID NOs:. Applicants respectfully submit that the above amendments and comments obviate and overcome the rejection and request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Claims 63, 64, 79, and 80 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Kemp (US Pat No. 5,536,648) as applied to claims in view of Shattuck-Eidens (US Pat No. 7,709,999).

Applicants respectively traverse this ground for rejection. As discussed above, claims 63, 64, 79, and 80 have been cancelled. Newly added claim 93 sets forth a method for detecting breast cancer in a patient which requires contacting a biological sample from a patient with at least two oligonucleotide primers in a polymerase chain reaction, wherein both of the oligonucleotide primers are specific for SEQ ID NO:62 and comprise at least about 10 contiguous nucleotides of SEQ ID NO:62. Newly added claim 102 sets forth a method for detecting breast cancer in a patient which requires contacting a biological sample, obtained from a patient, with an oligonucleotide probe specific for SEQ ID NO:62, wherein the oligonucleotide probe comprises at least about 15 contiguous nucleotides of SEQ ID NO:62.

Neither the Kemp nor the Shattuck-Eidens references, alone or in combination, provide Applicants' invention as recited in claims 93 or 102. Examination of the nucleotide sequence alignment of SEQ ID NO:20 of Shattuck-Eidens and Applicants' SEQ ID NO:62 indicates that the Shattuck-Eidens sequence does not contain the required 10 or 15 contiguous nucleotides of SEQ ID NO:62 necessary to fall within the scope of either claim 93 or 102. Addition of the Kemp reference does not overcome the deficiencies of the Shattuck-Eidens reference. Applicants respectfully submit that the above amendments and comments obviate and overcome the rejection and request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

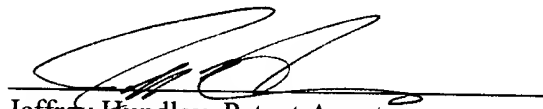
Claims 55 and 56 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Kemp (US Pat No. 5,536,648) as applied to claims in view of Billing-Medel (GenCore 4.5, Accession No. V31990, 5/7/1998).

As discussed above, claims 55 and 56 have been cancelled. Applicants respectfully submit that the above amendments obviate the rejection under 35 U.S.C. §103(a).

On the basis of the above amendments and remarks Applicants submit that each rejection has been addressed and overcome. Reconsideration of the application and its allowance are requested. Please credit any overpayment or charge any deficiency to Deposit Account No. 19-1090.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



Jeffrey Hundley, Patent Agent
Registration No. 42,676

Enclosures:

Postcard

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031

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Version with markings to show changes made

In the Claims:

Cancel claims 33, 44, and 53-88.

Add the following new claims:

--89. A method for detecting breast cancer in a patient comprising:

(a) contacting a biological sample from a patient with at least two oligonucleotide primers in a polymerase chain reaction, wherein said oligonucleotide primers are specific for SEQ ID NO:55 or the corresponding complement of SEQ ID NO:55 and at least one primer comprises at least about 10 contiguous nucleotides of SEQ ID NO:55; and

(b) detecting in said biological sample a polynucleotide sequence that amplifies in the presence of said oligonucleotide primers, thereby detecting breast cancer.

90. A method for detecting breast cancer in a patient comprising:

(a) contacting a biological sample from a patient with at least two oligonucleotide primers in a polymerase chain reaction, wherein said oligonucleotide primers are specific for SEQ ID NO:59 or the corresponding complement of SEQ ID NO:59 and at least one primer comprises at least about 10 contiguous nucleotides of SEQ ID NO:59; and

(b) detecting in said biological sample a polynucleotide sequence that amplifies in the presence of said oligonucleotide primers, thereby detecting breast cancer.

91. A method for detecting breast cancer in a patient comprising:

(a) contacting a biological sample from a patient with at least two oligonucleotide primers in a polymerase chain reaction, wherein said oligonucleotide primers are specific for SEQ ID NO:60 or the corresponding complement of SEQ ID NO:60 and at least one primer comprises at least about 10 contiguous nucleotides of SEQ ID NO:60; and

(b) detecting in said biological sample a polynucleotide sequence that amplifies in the presence of said oligonucleotide primers, thereby detecting breast cancer.

92. A method for detecting breast cancer in a patient comprising:

(a) contacting a biological sample from a patient with at least two oligonucleotide primers in a polymerase chain reaction, wherein said oligonucleotide primers are specific for SEQ ID NO:61 or the corresponding complement of SEQ ID NO:61 and at least one primer comprises at least about 10 contiguous nucleotides of SEQ ID NO:61; and

(b) detecting in said biological sample a polynucleotide sequence that amplifies in the presence of said oligonucleotide primers, thereby detecting breast cancer.

93. A method for detecting breast cancer in a patient comprising:

(a) contacting a biological sample from a patient with at least two oligonucleotide primers in a polymerase chain reaction, wherein said oligonucleotide primers are specific for SEQ ID NO:62 or the corresponding complement of SEQ ID NO:62 and at least one primer comprises at least about 10 contiguous nucleotides of SEQ ID NO:62; and

(b) detecting in said biological sample a polynucleotide sequence that amplifies in the presence of said oligonucleotide primers, thereby detecting breast cancer.

94. A method for detecting breast cancer in a patient comprising:

(a) contacting a biological sample from a patient with at least two oligonucleotide primers in a polymerase chain reaction, wherein said oligonucleotide primers are specific for SEQ ID NO:63 or the corresponding complement of SEQ ID NO:63 and at least one primer comprises at least about 10 contiguous nucleotides of SEQ ID NO:63; and

(b) detecting in said biological sample a polynucleotide sequence that amplifies in the presence of said oligonucleotide primers, thereby detecting breast cancer.

95. A method for detecting breast cancer in a patient comprising:

(a) contacting a biological sample from a patient with at least two oligonucleotide primers in a polymerase chain reaction, wherein said oligonucleotide primers are specific for SEQ ID NO:64 or the corresponding complement of SEQ ID NO:64 and at least one primer comprises at least about 10 contiguous nucleotides of SEQ ID NO:64; and

(b) detecting in said biological sample a polynucleotide sequence that amplifies in the presence of said oligonucleotide primers, thereby detecting breast cancer.

96. A method for detecting breast cancer in a patient comprising:

(a) contacting a biological sample from a patient with at least two oligonucleotide primers in a polymerase chain reaction, wherein said oligonucleotide primers are specific for SEQ ID NO:65 or the corresponding complement of SEQ ID NO:65 and at least one primer comprises at least about 10 contiguous nucleotides of SEQ ID NO:65; and

(b) detecting in said biological sample a polynucleotide sequence that amplifies in the presence of said oligonucleotide primers, thereby detecting breast cancer.

97. A method for detecting breast cancer in a patient comprising:

(a) contacting a biological sample from a patient with at least two oligonucleotide primers in a polymerase chain reaction, wherein said oligonucleotide primers are specific for SEQ ID NO:67 or the corresponding complement of SEQ ID NO:67 and at least one primer comprises at least about 10 contiguous nucleotides of SEQ ID NO:67; and

(b) detecting in said biological sample a polynucleotide sequence that amplifies in the presence of said oligonucleotide primers, thereby detecting breast cancer.

98. A method for detecting breast cancer in a patient, comprising:

(a) obtaining a biological sample from a patient;

(b) contacting said biological sample with an oligonucleotide probe specific for SEQ ID NO:55, wherein said oligonucleotide probe comprises at least about 15 contiguous nucleotides of SEQ ID NO:55; and

(c) detecting in said biological sample a polynucleotide sequence that hybridizes to said oligonucleotide probe, thereby detecting breast cancer in said patient.

99. A method for detecting breast cancer in a patient, comprising:

(a) obtaining a biological sample from a patient;

(b) contacting said biological sample with an oligonucleotide probe specific for SEQ ID NO:59, wherein said oligonucleotide probe comprises at least about 15 contiguous nucleotides of SEQ ID NO:59; and

(c) detecting in said biological sample a polynucleotide sequence that hybridizes to said oligonucleotide probe, thereby detecting breast cancer in said patient.

101. A method for detecting breast cancer in a patient, comprising:

(a) obtaining a biological sample from a patient;

(b) contacting said biological sample with an oligonucleotide probe specific for SEQ ID NO:60, wherein said oligonucleotide probe comprises at least about 15 contiguous nucleotides of SEQ ID NO:60; and

(c) detecting in said biological sample a polynucleotide sequence that hybridizes to said oligonucleotide probe, thereby detecting breast cancer in said patient.

101. A method for detecting breast cancer in a patient, comprising:

(a) obtaining a biological sample from a patient;

(b) contacting said biological sample with an oligonucleotide probe specific for SEQ ID NO:61, wherein said oligonucleotide probe comprises at least about 15 contiguous nucleotides of SEQ ID NO:61; and

(c) detecting in said biological sample a polynucleotide sequence that hybridizes to said oligonucleotide probe, thereby detecting breast cancer in said patient.

102. A method for detecting breast cancer in a patient, comprising:

- (a) obtaining a biological sample from a patient;
- (b) contacting said biological sample with an oligonucleotide probe specific for SEQ ID NO:62, wherein said oligonucleotide probe comprises at least about 15 contiguous nucleotides of SEQ ID NO:62; and
- (c) detecting in said biological sample a polynucleotide sequence that hybridizes to said oligonucleotide probe, thereby detecting breast cancer in said patient.

103. A method for detecting breast cancer in a patient, comprising:

- (a) obtaining a biological sample from a patient;
- (b) contacting said biological sample with an oligonucleotide probe specific for SEQ ID NO:63, wherein said oligonucleotide probe comprises at least about 15 contiguous nucleotides of SEQ ID NO:63; and
- (c) detecting in said biological sample a polynucleotide sequence that hybridizes to said oligonucleotide probe, thereby detecting breast cancer in said patient.

104. A method for detecting breast cancer in a patient, comprising:

- (a) obtaining a biological sample from a patient;
- (b) contacting said biological sample with an oligonucleotide probe specific for SEQ ID NO:64, wherein said oligonucleotide probe comprises at least about 15 contiguous nucleotides of SEQ ID NO:64; and
- (c) detecting in said biological sample a polynucleotide sequence that hybridizes to said oligonucleotide probe, thereby detecting breast cancer in said patient.

105. A method for detecting breast cancer in a patient, comprising:

- (a) obtaining a biological sample from a patient;
- (b) contacting said biological sample with an oligonucleotide probe specific for SEQ ID NO:65, wherein said oligonucleotide probe comprises at least about 15 contiguous nucleotides of SEQ ID NO:65; and

(c) detecting in said biological sample a polynucleotide sequence that hybridizes to said oligonucleotide probe, thereby detecting breast cancer in said patient.

106. A method for detecting breast cancer in a patient, comprising:

- (a) obtaining a biological sample from a patient;
- (b) contacting said biological sample with an oligonucleotide probe specific for SEQ ID NO:67, wherein said oligonucleotide probe comprises at least about 15 contiguous nucleotides of SEQ ID NO:67; and
- (c) detecting in said biological sample a polynucleotide sequence that hybridizes to said oligonucleotide probe, thereby detecting breast cancer in said patient.--